

REMARKS/ARGUMENTS

Objection to the Drawings

Applicant acknowledges the objections to the drawings and provide drawings with appropriate reference numbers indicated thereon.

Objection to the Specification: Description of Drawings

Applicant has amended the specification to refer to the drawings and numbered elements with respect thereto. To simplify and expedite prosecute, a substitute specification is submitted as per a telephone message left and returned by the Examiner on October 31, 2001. No new matter is added in the substitute specification.

Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

The Examiner rejects Claims 4-7, 21-25, 29 and 30 under §112, second paragraph for allegedly failing to further limit the claimed invention structurally, the Examiner noting that such claims are “functional in scope”. In response thereto, Applicant respectfully traverses the Examiner’s rejection of claims.

There is nothing intrinsically wrong in defining something by what it does rather than by what it is. In re Hallman, 210 USPQ 609 (CCPA 1981). A claim is not indefinite merely because it is functional. In re Miller, 169 USPQ 597 (CCPA 1971); Ex parte Ponsford, 575 PCTJ A-13 (POBA 1982); or functional at the point of novelty. Ex parte Roggenburk, 172 USPQ 82 (POBA 1970). It is well established that the use of a functional term is not objectionable where one skilled in the art can determine from the disclosure provided in the specification what subject matter is regarded as the invention. See In re Watson, 186 USPQ 11 (CCPA 1975).

For the foregoing reasons, Applicant respectfully requests reconsideration and withdrawal of all §112, second paragraph rejections of the above-referenced claims.

Rejection of Claims Under 35 U.S.C. §102

The Examiner rejects Claims 1-8, 10-12, 15, 20-25 and 27-30 under 35 U.S.C. §102(b) as being anticipated by Cragg. The Examiner contends that Cragg discloses a device comprising a catheter, a mechanical element, a motor and a blocking element. Applicant respectfully traverses the Examiner's rejection for the reasons as set forth below.

To constitute anticipation, all material elements of the claim must be found in one prior art source. In re Marshall, 198 USPQ 344 (CCPA 1978); In re Kalm, 154 USPQ 10 (CCPA 1967). Although Cragg describes a catheter, a mechanical element, a motor, and a blocking element, Cragg's catheter is an introducer (rather than an "infusion") catheter that does not employ mechanical motion of the catheter itself. The mechanical device in Cragg uses a rotating brush connected to a motor by a drive shaft. In contrast, the present invention is directed to a catheter where the mechanical motion is incorporated into the catheter itself. Unlike the Cragg device, in the present invention there is no separate rotating brush emanating from a catheter.

Moreover, the Cragg patent makes no mention of a motor controller, much less a programmable motor controller, to allow one to control the speed of mechanical action, activation times, or inactivation times. The Cragg motor is hand held and activated by the physical act of pushing a button on the motor housing. Furthermore, due to its construction and mode of operation, Cragg is not compatible with long term indwelling treatment, as are various embodiments of the present invention.

One blocking element described in the Cragg patent is an inflatable balloon which is expensive, complex to manufacture, and requires a lumen for a guide wire and a lumen for inflation, in addition to the balloon. Due to the presence of such multiple lumens, Cragg's inflatable balloon catheter has such a large diameter that inserting it through Cragg's mechanical device is unwieldy and impractical. In contrast, the preferred blocking element of the present invention utilizes a simple guide wire that is much smaller, less expensive, preferably has a variable stiffness, and may be utilized to promote the mechanical action of the catheter itself, as opposed to reliance on Cragg's rotating brush.

Cragg also describes an alternative blocking element/obstruction mechanism as “an expandable wire basket” (Col. 8, line 51) and a “guide wire mounted basket and mesh assembly” (Col 8, line 55.) It is believed that Cragg is referring to a Dormier-type spiral wire basket. In contrast, the present invention is directed to a deformable mesh braid - not a “wire basket” and has a membrane disposed in the interstitial spaces of the braid. Cragg does not disclose, for example, the use of an impermeable elastomeric membrane within the interstices of a mesh braid, as is present in a preferred embodiment of the present invention. In fact, Cragg teaches away from the use of such an impermeable membrane by stating that his wire basket may restrict blood flow due to fibrin fragments lodging in the wire basket. The blocking element of Cragg differs from the blocking element of the present invention by its use of distinct materials and structures, including the absence of any suggestion to use an elastomeric membrane in conjunction with such blocking element.

Most importantly, however, Cragg fails to teach or suggest the present device and method which is directed to a catheter that itself moves within a patient's vessel in order to disrupt a blood clot located therein, such catheter further having a plurality of apertures that provide for delivery of desired thrombolytic agents therethrough. The Cragg device is not designed for long term indwelling within a patient and the fast rotating brush of Cragg would be incompatible with long term indwelling time periods, given that the rotating brush would cause damage to the vessel itself if left within the patient rotating in the manner described by Cragg. In contrast, the present invention provides for a gentle, clot disruptive action generated by movement of the catheter which directly contacts clots located within a vessel, such gentle movement capable of disrupting such clots without causing damage to the patient's vessel.

For the foregoing reasons, Applicant respectfully requests the Examiner to reconsider and withdraw all rejection of claims predicated upon the Cragg reference.

Rejection of Claims 20-30 Under 35 U.S.C. §102 as Being Anticipated by Mische et al.

The Examiner contends that Mische et al. disclose a device comprising a means to increase the surface area of a clot and a means to provide a mechanical action. Applicant respectfully traverses the Examiner's rejections for the reasons as set forth below.

Mische et al. disclose a complex two catheter thrombolysis system that shares little resemblance to the present invention. In Mische et al., the means of increasing the surface area, as well as the mechanical action, comprises an ultrasonic band, which vibrates or resonates in the ultrasound frequency range of 10 KHz (10,000 cycles/second) and greater. This is problematic due to the difficulty in controlling the amount of ultrasonic vibratory energy reaching an active segment, as there is loss of energy with contact of the ultrasonic element and the catheter, contact between the catheter and the vessel wall, contact of either with the thrombus, and due to the heat generated with contact of the element with surrounding tissue. These difficulties make it impossible to impart significant mechanical motion throughout an extended length of the Mische et al. catheter. Moreover, the frequencies disclosed as useful by Mische et al. would create minimal movement of the catheter and thus would have little effect on a thrombus. In a medium to large sized vessel, the Mische et al. device would occupy only a small portion of the cross sectional area of the vessel, and the thrombus. The majority of a thrombus would not come into contact with the catheter and would not be affected by the minimal motion of it.

In contrast, in a preferred embodiment of the present invention, the desired mechanical motion is less than one cycle per second, and in various embodiments, is directed to rotational movement of the catheter at less than about 55 RPMs. The energy transfer is much more predictable and the mechanical motion much more substantial than that disclosed by Mische et al. The motion imparted to the present catheter is much more effective in increasing the surface area of a clot, as compared to the minimal movement that may be generated by the ultrasonic band of Mische et al.

Rejection of Claims Under 35 U.S.C. §103(a)

The Examiner rejects Claims 9, 13, 14 and 16-19 under §103(a) as being unpatentable over Cragg. The Examiner contends that Cragg discloses the invention substantially as claimed, however, the Examiner admits that Cragg does not disclose the use of a braided catheter, pump or manual motor controls. The Examiner contends that such elements, however, are well established in the prior art and that to have utilized these elements with the Cragg device would have been within the

level of skill since such a modification would allegedly have allowed a greater control of the fluid flow and motor speed. Applicant respectfully traverses the Examiner's obviousness rejection for the reasons as set forth below.

Applicant submits that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggesting supporting the combination. ACS Hospital Systems v. Montofiore Hospital, 221 USPQ 929, 933 (Fed.Cir. 1974). Before obviousness may be established, the Examiner must show that there is either a suggestion in the art to produce the claimed invention or a compelling motivation based on sound scientific principles. Ex parte Kranz, 19 USPQ 2d 1216, 1218 (BPAI 1981). Applicant respectfully submits that the Examiner has not established a prima facie case of obviousness because the Cragg reference is admittedly devoid of any suggestion to use a braided catheter, a pump or the motor controls set forth in the rejected claims. It appears that in the present case the only suggestion for the Examiner's combination of the teachings in Cragg improperly stems from the Applicant's own disclosure and not from the cited reference. At best, the Examiner's comments regarding obviousness appear to amount to an assertion that one of ordinary skill in the relevant art would have been able to arrive at Applicant's invention because they would have had the necessary skills to carry out the requisite process steps, provided that they possessed the unique device as set forth in the present claims. This is an inappropriate standard for obviousness. In brief, the Cragg reference, alone or in combination with any other prior art, does not provide an impetus necessary to cause one skilled in the art to rely upon the Cragg reference in the way the Examiner has done.

It is well established that an evaluation of the obviousness or non-obviousness of claims must not be made with the benefit of hindsight using the present application as a blueprint to reconstruct the claimed invention from the references. See Interconnect Planning Corporation v. Feil, 227 USPQ 543 (Fed.Cir. 1985). Applicant submits that the Examiner's examination of the present invention should not be predicated upon the obviousness of particular features but rather, should be based upon an evaluation of the invention as a whole. Again, given the lack of any suggestion or teaching in Cragg to use a catheter which itself provides mechanical disruption of a thrombus, and which incorporates the use of features admittedly absent in Cragg (e.g., braided catheter, pump,

control motor, the impossibility that use of the Cragg device could accomplish the long term indwelling procedures contemplated by the present invention, etc.), leads to the conclusion that the Cragg reference, alone or in combination, does not render the present invention obvious.

In arguing that it would have been obvious to make and use the claimed invention given the teachings of Cragg, the Examiner seems in essence to be stating that it would have been "obvious to try" modifying various parameters, and indeed selecting entirely different mechanical structures having distinct identifying features and capabilities, in order to produce the claimed invention. The Federal Circuit has provided clear direction with respect to arguments based on an "obvious to try" theory. The court has held that an "obvious to try" situation exists when a general disclosure may pique a scientists curiosity, such that further investigation might be done as the result of a disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued. In re Eli Lilly & Co., 14 USPQ 2d 1741, 1743 (Fed.Cir. 1990). The court held, however, that "obvious to try" is not to be equated with obviousness under 35 U.S.C. §103. See Gillette Co. v. S.C. Johnson & Son, Inc., 16 USPQ 2d 1923, 1928 (Fed.Cir. 1990). For the foregoing reasons, Applicant respectfully submits that Cragg does not provide sufficient suggestions or teachings to direct one of ordinary skill in the art to make the present invention and as such, Applicant respectfully requests the Examiner to withdraw all §103 rejections predicated thereon.

Obviousness under 35 U.S.C. §103 turns on whether the prior art, including the knowledge available to one of ordinary skill in the art, provides some suggestion or motivation to combine the known elements. See Fromson v. Advance Offset Plate, Inc., 775 F.2d 1549, 1556, 225 USPQ 26, 31 (Fed. Cir. 1985). There is no teaching or suggestion whereby a person of ordinary skill would have been led to select these mechanical and electrical structures and concepts in Cragg to arrive at the present invention. To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction -- an illogical and inappropriate process by which to determine patentability. W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). A rejection based on §103 clearly must rest on a factual basis, and these facts must be interpreted

without hindsight reconstruction of the invention from the prior art. In making this evaluation, all facts must be considered. The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis. "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." In re Fritch, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992). Moreover, the motivating suggestion must be explicit. Winner International Royalty Corporation v. Wang, 48 USPQ2d 1139 (D.C., D.C. 1998) ("there must have been some explicit teaching or suggestion in the art to motivate one of even ordinary skill to combine such elements so as to create the same invention"). That individual elements of the inventions are old can be found in the prior art is irrelevant. Grain Processing Corp. v. American Maize Products Co., 5 USPQ2d 1788 (Fed. Cir. 1988). The Examiner should not be able to pick and choose individual elements from multiple references to recreate the invention. Polaroid Corp. v. Eastman Kodak Co., 229 USPQ 561 (Fed. Cir.), *cert. denied*, 479 U.S. 850 (1996). In determining the scope and content of the prior art, and determining whether the prior art suggested the claimed invention, the references "must be read as a whole and consideration must be given where the references diverge and teach away from the claimed invention". Akzo N.V. v. United States Int'l Trade Commission, 1 USPQ2d 1241 (Fed. Cir. 1986) *cert denied*, U.S. 909 (1987); Panduit Corp. v. Dennison Mfg. Co., 1 USPQ2d 1593 (Fed. Cir.), *cert denied*, 481 U.S. 1052 (1987).

In the event the Examiner persists in such §103 rejection, Applicant respectfully requests that the Examiner provide an affidavit in accordance with 37 CFR §1.104(d)(2). Such section requires that when a rejection in an application is based upon facts within the personal knowledge of the Examiner, the data relied upon should be as specific as possible, and the reference must be supported, when called for by the applicant, by the affidavit of the Examiner, such affidavit to be subject to contradiction or explanation by affidavits of the applicant or other persons. As such, Applicant also respectfully requests the opportunity to respond to any such affidavit of the Examiner if one is submitted.

Prior Art Made of Record, But Not Relied Upon

Applicant has reviewed the prior art made of record, but not relied upon to reject any claims. Applicant does not believe that any of such references, alone or in combination with any of the other cited references, would render the present invention obvious.

Applicant submits the accompanying Supplemental Information Disclosure Statement citing the Clark, III patent directed to an expanded mesh catheter. Clark, III does not teach or disclose the use of a catheter whereby rotation or movement of the catheter is relied upon to break up a blood clot in a vein or artery. Clark, III is solely directed to inserting a catheter through a clot, expanding a braided mesh end portion of the catheter, and then withdrawing the catheter carrying the clot with it (see Clark, III, col. 2, lines 24-31). Moreover, Clark, III appears to teach only a short flexible portion 10 of a much longer guide. In contrast, the present invention preferably relies upon a catheter that is flexible along its entire length. Nor does Clark, III teach or suggest the use of a catheter having a plurality of apertures provided therein for the delivery of lytic agents to a clot. Indeed, Clark, III teaches the use of an expanding mesh catheter simply to physically "pull a clot through a vessel" when the catheter is withdrawn. In one embodiment, the present invention is directed to a catheter which itself disrupts a clot by mechanical (e.g., rotational) action of the catheter itself and where the catheter is purposefully left to dwell within a person's vessel for an extended period of time in order that such mechanical action of the catheter can dislodge clots contained within such vessel. The expanded mesh portion of the present invention is also relied upon principally to block the vessel and thus allow more concentrated delivery of lytic agents to desired thrombic regions.

Applicant's counsel requests the courtesy of a telephone interview in the event the Examiner still believes that one or more claims are not in a condition for allowance. Applicant's counsel can be reached directly at (303) 863-2977.

Attached hereto is a marked up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version With Markings to Show Changes Made."**

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Based upon the foregoing, Applicant believes that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1, 16, 19, 20 and 31 have been amended as follows:

Claims 15 and 18 have been cancelled.

1. (Once Amended) A thrombolytic device comprising:
a catheter having a catheter wall, a proximal end, a distal end, and at least one lumen;
[a mechanical element, having a near end and a far end, said near end connected to said distal
end of said catheter and extending therefrom; and]
a motor attached to said proximal end of said catheter for imparting motion to said
[mechanical element] catheter.

Claim 15 has been cancelled.

16. (Once Amended) A thrombolytic device for use with a pharmacological agent
comprising:
a catheter having a catheter wall, a proximal end, a distal end, and at least one lumen;
[a mechanical element extending from said distal end of said catheter;]
a motor attached to said proximal end of said catheter for imparting motion to said
[mechanical element] catheter;
a pharmacological delivery conduit with a first end and a second end, said first end
operatively connected to said lumen at said proximal end of said catheter;
a pump for delivering a pharmacological agent, said pump operatively connected to said
second end of said conduit.

Claim 18 has been cancelled.

19. (Once Amended) A thrombolytic device as in claim 16, [18, wherein said] further comprising an occlusion mechanism [is] selected from the group consisting of a inflatable balloon, a deformable mesh braid with a membrane, and a malecot with a membrane, said occlusion mechanism operatively associated with said catheter.

20. (Once Amended) A pharmomechanical device, comprising:
means to increase the surface area of a clot in a vascular structure such that said clot can be dissolved by a lytic agent; and
means for providing mechanical action throughout a length of a vessel for a prolonged period of time while said lytic agent is acting, said mechanical means comprising a serpentine catheter corkscrew substantially incapable of damaging an endothelium of said vascular structure.

31. (Once Amended) A method for ameliorating a clot in a patient's blood vessel, comprising:
administering to a patient an amount of contrast medium to determine the extent of a thrombus in the patient's blood vessel;
selecting a catheter having an appropriate length segment, said length segment having a mechanically active portion and an aperture-containing portion, said step of selecting conducted so that said length segment spans the entire length of a clot contained within said patient's blood vessel;
inserting a catheter into said patient's blood vessel;
deploying a distal occlusion element to reduce undesired passage of a thrombolytic drug from said blood vessel;
programming a motor controller to obtain desired periods of activation and inactivation;
intermittently activating said mechanically active segment to remove said clot from said blood stream; [and]
infusing a desired thrombolytic agent through said catheter substantially simultaneously with said step of activating said mechanical segment; and

observing the patient in a location remote from the patient during at least one of said steps of intermittently activating and infusing.

Claims 32-55 have been added as follows:

32. (Added) A method for ameliorating a clot in a patient's blood vessel as set forth in Claim 31, wherein said step of intermittently activating said mechanically active segment is accomplished by activating an infusion pump which delivers said thrombolytic agent.

33. (Added) The method as set forth in Claim 31, further comprising monitoring said thrombolysis over a period of time extending from at least 20 minutes after said step of inserting.

34. (Added) A thrombolytic device comprising:
a catheter having a proximal end, an elongated mid-section and a distal end, said distal end comprising a deformable mesh braid having interstitial spaces therein, and a membrane disposed in said interstitial spaces, said distal end operatively associated with a movable core guide wire that is movable between an extended and a retracted position, wherein when said core guide wire is in said retracted position, said mesh braid is deformed into an expanded disk-like structure so as to occlude a vessel through which said catheter is inserted;

a means for repeatedly rotating said catheter within said vessel in a manner such that said catheter contacts a clot within said vessel and said clot is disrupted by said rotating.

35 (Added) The catheter as set forth in Claim 33, wherein said catheter is rotatable about said core wire.

36. (Added) The device as set forth in Claim 34, wherein at least said mid-section of said catheter has a plurality of apertures extending therethrough.

37. (Added) A method to perform long segment thrombolysis comprising:

(a) performing an interventional procedure on a patient in order to place a device comprising a catheter having a proximal end, an elongated mid-section and a distal end, said distal end comprising a deformable mesh braid having interstitial spaces therein, and a membrane disposed in said interstitial spaces, said distal end operatively associated with a movable core guide wire that is movable between an extended and a retracted position, wherein when said core guide wire is in said retracted position, said mesh braid is deformed into an expanded disk-like structure so as to occlude the lumen of a vessel through which said catheter is inserted, said catheter having a plurality of apertures therethrough to facilitate the delivery of thrombolytic agents;

(b) infusing through said catheter a desired thrombolytic agent;

(c) performing mechanical disruption of a blockage in a vascular lumen by repeatedly rotating said catheter at a rotational speed of less than about 55 RPMs;

(d) maintaining said device within said patient for at least one hour; and

(e) removing said device from said patient.

38. (Added) A thrombolytic device comprising a first mechanically active segment and a second aperture containing segment, said first and second segments spanning an entire length of a clot contained within a patient's vessel, said first segment operatively associated with a drive motor so as to rotate said first and second segments, said second segment being operatively associated with an infusion pump through which a thrombolytic agent is conveyed.

39. (Added) The method as set forth in Claim 37, wherein said catheter is rotated in both clockwise and counter-clockwise directions.

40. (Added) The device as set forth in Claim 34, wherein said catheter has a serpentine configuration.

41. (Added) The device as set forth in Claim 20, wherein an intermittent motion of the catheter is provided by a pump that delivers a lytic agent in programmable pulses.

42. (Added) The device as set forth in Claim 41, wherein a frequency and a duration of said pulses are programmable.

43. (Added) The device as set forth in Claim 34, wherein said catheter rotates at less than about 200 RPMs.

44. (Added) The device as set forth in Claim 34, wherein said catheter rotates at less than about 55 RPMs.

45. (Added) The method as set forth in Claim 31, wherein said step of intermittently activating comprises operation of said mechanically active segment for about 2 seconds and then remaining inactive for about 5 minutes.

46. (Added) The method as set forth in Claim 31, wherein said step of infusing is repeatedly performed with a time interval between individual infusions being at least 5 minutes apart.

47. (Added) The method as set forth in Claim 31, wherein said step of infusing is repeatedly performed with a time interval between individual infusions being at least 15 minutes apart.

48. (Added) The method as set forth in Claim 31, wherein said step of infusing is repeatedly performed with a time interval between individual infusions being at least 30 minutes apart.

49. (Added) The method as set forth in Claim 31, wherein said intermittently activating step comprises mechanical action for between about .1 second and 60 seconds and a period of inactivation of more than 5 seconds and up to about 20 minutes.

50. (Added) A method for treating a clot in a patient's vessel, comprising:
inserting a catheter into a patient's blood vessel;
occluding a desired portion of said patient's blood vessel to reduce undesired passage of a lytic agent beyond a desired position along said vessel;
infusing said catheter with a lytic agent;
providing a gentle mechanical rotation of said catheter at a speed of less than about 55 RPMs;
intermittently ceasing mechanical rotation of said catheter for a time period of at least about 3 minutes and providing mechanical action of said catheter thereafter in time intervals of at least about 3 seconds.

51. (Added) The method as set forth in Claim 50, wherein said step of intermittently ceasing mechanical rotation is controlled using a programmable controller.

52. (Added) The method as set forth in Claim 31, wherein said step of intermittently activating comprises rotating said catheter between about 1 and 300 times per minute.

53. (Added) The device as set forth in Claim 16, wherein said catheter has apertures provided therein along a length of from 20 to 60 cm as measured from said distal end.

54. (Added) The method as set forth in Claim 31, wherein said step of intermittently activating comprises movement of the catheter, said movement selected from the group consisting of a longitudinal wave-like motion and an axial rotation motion.

55. (Added) The method as set forth in Claim 31, further comprising the step of monitoring said method during said step of infusing.